CARVYKTI® ▼3.2 × 10^6– 1.0 × 10^8 cells dispersion for infusion

ABBREVIATED PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): ciltacabtagene autoleucel

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

INDICATION(S): Treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least one prior therapy, including an immunomodulatory agent and a proteasome inhibitor, have demonstrated disease progression on the last therapy, and are refractory to lenalidomide.

DOSAGE & ADMINISTRATION: Must be administered in a qualified treatment centre. Therapy should be initiated under the direction and supervision of a healthcare professional experienced in the treatment of haematological malignancies and trained for administration and management of patients treated with CARVYKTI.
Adults: Treatment consists of a single dose for infusion. The target dose is 0.75 x 10^6 CAR-positive viable T cells/kg of body weight (not exceeding 1.0 × 10^8 CAR-positive viable T cells). **Bridging therapy:** HCP must consider bridging therapy before infusion with CARVYKTI to reduce tumour burden or stabilise the disease. **Pre-treatment (lymphodepleting regimen):** A lymphodepleting regimen of cyclophosphamide 300 mg/m^2 intravenous and fludarabine 30 mg/m^2 intravenous should be administered daily for 3 days. CARVYKTI infusion should be administered 5 to 7 days after the start of the lymphodepleting regimen. For additional guidance see corresponding SmPC of cyclophosphamide and fludarabine. **Premedication:** The following pre-infusion medications should be administered to all patients 30 to 60 minutes prior to CARVYKTI infusion: Antipyretic (oral or intravenous paracetamol 650 to 1,000 mg), antihistamine (oral or intravenous diphenhydramine 25 to 50 mg or equivalent). Systemic corticosteroids should be avoided.
Children: not established.
Elderly: No dose adjustment is required.

CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients. Contraindications of the lymphodepleting chemotherapy and supportive therapy should be considered.

SPECIAL WARNINGS & PRECAUTIONS:
Please refer to SmPC for information on the following special warnings and precautions: Traceability; Autologous Use; Clinical Assessment prior to infusion; Rapidly Progressing Disease; Monitoring after infusion; Cytokine release syndrome (CRS); Neurologic toxicities; Prolonged and recurrent cytopenias; Serious infections and febrile neutropenia; Viral reactivation; Hypogammaglobulinaemia; Immune-mediated enterocolitis; Secondary malignancies including of myeloid and T-cell origin; Interference with virological testing; Blood, organ, tissue and cell donation; Hypersensitivity; Long-term follow-up.

SIDE EFFECTS:
Very common: Bacterial infection, Upper respiratory tract infection, Viral infection, Pneumonia, Neutropenia, Thrombocytopenia, Anaemia, Leukopenia, Lymphopenia, Coagulopathy, Cytokine release syndrome, Hypogammaglobulinaemia, Hypocalcaemia, Hypophosphataemia, Decreased appetite, Hypokalaemia, Hypoalbuminaemia, Hyponatraemia, Hypomagnesaemia, Hypoferritinemia, Encephalopathy, Immune effector cell-associated neurotoxicity syndrome, Motor dysfunction, Dizziness, Headache, Sleep Disorder, Tachycardia, Hypotension, Hypertension, Haemorrhage, Hypoxia, Dyspnoea, Cough, Diarrhoea, Nausea, Vomiting, Constipation, Musculoskeletal pain, Pyrexia, Fatigue, Chills, Oedema, Pain, Transaminase elevation, Gamma-glutamyltransferase increased. **Common:** Sepsis, Gastroenteritis, Urinary Tract Infection, Fungal infection, Secondary malignancy of myeloid origin, Febrile neutropenia, Lymphocytosis, Haemophagocytic

lymphohistiocytosis, Delirium, Personality changes, Aphasia, Cranial nerve palsies, Paresis, Ataxia, Neuropathy peripheral, Tremor, Neurotoxicity, Cardiac arrhythmias, Thrombosis, Capillary leak syndrome, Abdominal pain, Immune-mediated enterocolitis, Hyperbilirubinaemia, Rash, Renal failure, C-reactive protein increased, Blood alkaline phosphatase increased. **Uncommon**: Guillain-Barre syndrome, Secondary malignancy of T-cell origin.

Refer to SmPC for further information on side effects LEGAL CATEGORY: Prescription Only Medicine (POM)

PRESENTATION: Each CARVYKTI infusion bag contains ciltacabtagene autoleucel cell dispersion containing 3.2×10^6 to 1×10^8 CAR-positive viable T cells suspended in a cryopreservative solution. An infusion bag contains 30 mL or 70 mL of dispersion for infusion.

MARKETING AUTHORISATION NUMBER: EU/1/22/1648/001

MARKETING AUTHORISATION HOLDER: Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

FURTHER INFORMATION IS AVAILABLE FROM: Janssen Sciences Ireland UC, Barnahely, Ringaskiddy, IRL – Co. Cork P43 FA46

Prescribing information updated: July 2025

Adverse events should be reported. ▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance, Website: www.hpra.ie. Adverse events should also be reported to Janssen Sciences Ireland UC, a Johnson & Johnson Company, on 0044 1494 567447 or at dsafety@its.jnj.com.